

Keep a close eye on vacuum-assisted wound closure

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AFTER BEING SERIOUSLY injured in a fall, a patient had his leg amputated. During his recovery, he was prescribed anticoagulants to prevent venous thromboembolism. Two weeks after the amputation, he began treatment with negative-pressure wound therapy (NPWT) to promote healing. During a dressing change while undergoing NPWT, he experienced serious bleeding from several areas in the wound. He later died, reportedly from severe hemorrhage and possible acute myocardial infarction. Further follow-up revealed that complications associated with bleeding initially started at surgery, before the NPWT was used.

What went wrong?

A noninvasive mechanical wound care therapy, NPWT assists in wound healing by applying controlled localized negative pressure to a wound's surface and margins. As specified in the device labeling, NPWT is applied to a special foam dressing packed in the wound cavity or over a flap or graft. Vacuum pressure helps remove fluids and infectious material from the wound, which encourages healing.

If a patient is undergoing NPWT, closely monitor him for signs and symptoms of overt and occult bleeding if he meets any of these criteria:

- He's actively bleeding.
- He's receiving anticoagulant therapy.
- He has weakened, irradiated, or sutured blood vessels or organs in proximity to the wound.

The patient in this case was especially vulnerable to hemorrhage during NPWT because he was actively bleeding from the surgical site and he was undergoing anticoagulant therapy.

What precautions can you take?

If NPWT is prescribed for your patient, take these steps to protect him from bleeding.

- Assess him for preexisting bleeding disorders or use of anticoagulants or other medications or herbs that prolong bleeding times, such as nonsteroidal anti-inflammatory drugs, aspirin, or ginkgo biloba.
- Carefully observe him for unusual or excessive bleeding after surgery.
- Make sure you know the contraindications and precautions for NPWT, including difficult wound hemostasis.
- Use protective barriers (such as gauze impregnated with petrolatum) to protect weakened, irradiated, or sutured blood vessels or organs that are close to areas being treated with NPWT.
- Know and follow your facility's policy and procedure for using NPWT.
- Review and follow the device manufacturer's instructions for use, including the appropriate negative-pressure setting recommended for the type of wound.
- Monitor patient for complications while device is in use. ◀▶

SELECTED REFERENCE

Mendez-Eastman S. Using negative-pressure wound therapy for positive results. *Nursing* 2005. 35(5):48-50, May 2005.

Although you need to support the adverse event-reporting policy of your health care facility, you may voluntarily report a medical device that doesn't perform as intended by calling MedWatch at 1-800-FDA-1088 (fax: 1-800-FDA-0178). The opinions and statements in this report are those of the author and may not reflect the views of the Department of Health and Human Services. Beverly Albrecht Gallaresi, RN, BS, MPH, is a nurse-consultant at the Center for Devices and Radiological Health at the Food and Drug Administration in Rockville, Md., and coordinates Device Safety.

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